DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 8, 2014

SpineFrontier, Incorporated
% Meredith May, MS, RAC
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K141337
Trade/Device Name: SpineFrontier Arena-C® Cervical Intervertebral Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 19, 2014
Received: July 10, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K141337

Device Name
SpineFrontier Arena-C® Cervical Intervertebral Body Fusion System

Indications for Use *(Describe)*

The Arena-C® Cervical Intervertebral Body Fusion System is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc.

The SpineFrontier Arena-C® Cervical Intervertebral Body Fusion System is intended to be used with supplemental spinal fixation system(s) cleared for use in the cervical spine (example: Anterior Cervical Plate Fixation).

Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (9/13)
6740 EF

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FORM FDA 3881 (9/13)

5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915, U.S.A.
Contact Person:	Paul L. Speidel Regulatory Affairs Manager Tel: 978.279.9272 Fax: 978.232.3991 PaulSpeidel@spinefrontier.com
Prepared by:	Meredith May MS, RAC Empirical Consulting Tel: 719-337-7579 Mmay@EmpiricalTesting.com
Date Summary was Prepared:	28-Aug-14
Trade or Proprietary Name:	Arena-C®
Common or Usual Name:	Cervical Interverterbal Body Fusion System
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices – Anterior Spine Device Branch

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

This 510(k) Submission is seeking add new sizes to the previously cleared Arena-C device. The SpineFrontier Cervical Interbody Fusion Device System (Arena-C® Cervical Intervertebral) is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. The system is comprised of devices made of Peek Optima®, with various heights to fit the anatomical needs of a wide variety of patients. The device has raised contours on the superior and inferior surfaces that will resist the device movement following implantation.

INDICATIONS FOR USE

The Arena-C® Cervical Intervertebral Body Fusion System is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc.

The SpineFrontier Arena-C® Cervical Intervertebral Body Fusion System is intended to be used with supplemental spinal fixation system(s) cleared for use in the cervical spine (example: Anterior Cervical Plate Fixation).

Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The indications for use for the Arena-C® Cervical Intervertebral Fusion Device is identical to that of the previously cleared devices.

TECHNICAL CHARACTERISTICS

Arena-C® Cervical Intervertebral Fusion Device is made from material that is identical to the previously cleared and predicate device. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1: Previously cleared and predicate devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K090064	Copperhead System	Eminent Spine
K110733	Daytona Anterior Cervical Cage	SpineNet
K113518	Arena-C® Cervical Intervertebral Fusion Device	SpineFrontier

PERFORMANCE TESTING SUMMARY

Engineering rationale and finite element analysis were used to demonstrate that the modifications to the Arena-C Cervical Intervertebral Fusion Device do not generate new worst case compared to the predicate device.

CONCLUSION

The subject modified is Arena-C® Cervical Intervertebral Fusion Device very similar to previously cleared Arena-C® Cervical Intervertebral Fusion Device and the referenced predicate device. The subject Arena-C® Cervical Intervertebral Fusion Device has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance analysis lead to the conclusion that the Arena-C® Cervical Intervertebral Fusion Device is substantially equivalent to the predicate devices.